

# Compounding for Animal Patients: Background and USP's Role

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Compounding need is great

Interdisciplinary training/resources defi

- Veterinarians  $\neq$  pharmaceutical compounding
- Pharmacists  $\neq$  veterinary pharmacotherapy

Compounds prepared using non-standard methods

- Pharmacies
- Veterinary practices
- Other



## Driven by economic factors

- Shortages
- Cash payment/no third party reimbursement

## Commoditization of compounds

- Purchased and resold just as approved drugs

Drug Quality and Security Act of 2013 does not apply to veterinary compounding

## Therapeutic failure

- Composition
- Stability
- Quality and performance

## Toxicity

- Contamination
- Potency
- Suspending vehicle
- Preservatives
- Flavors/sweeteners
- Dyes

## Drug Entity “death”

- Compound failure attributed to drug failure
  - e.g. pergolide suspension for PPID



**Conclusions and Clinical Relevance**—Results indicated that pergolide mesylate was unstable after compounding in an aqueous vehicle and that storage conditions had an effect on stability of the compounded formulation. Compounded pergolide formulations in aqueous vehicles should be stored in a dark container, protected from light, and refrigerated and should not be used > 30 days after produced. Formulations that have undergone a color change should be considered unstable and discarded. (J Am Vet Med Assoc 2009;234:385–389)

## Outreach

- Live Meetings/Workshops
- Webinars
- Publications

## Standards

- Ingredients
- Processes
- Acceptance criteria

2<sup>nd</sup> Veterinary Stakeholders Meeting

AVMA Webinar on Compounding February 7, 2014

Compounding Forums at National Symposia:

- ACVIM
- SVHP
- IACP
- NABP

Veterinary pharmacy electives

Peer-reviewed publications

Stimuli articles

## Formulas

- Standardized with “vetted”:
  - Pharmaceutical grade ingredients
  - Explicit compounding procedure
  - BUD from stability-indicating assay
  - Packaging, labeling and storage directives

## Process and Acceptance Criteria

- Procedures and tests to verify quality

## Standard Setting

Product  
Monographs

Substance  
Monographs

Preparation  
Monographs

General  
Chapters

Outreach

## Product Monographs

- AMDUCA
  - FDA's guidance -- approved product
- Known potency range
- Known dosing metric (base or salt)
- Exclusivity retained
- Need product monographs for all approved veterinary drugs

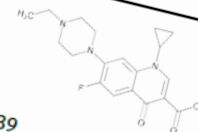


## Current Monograph Universe

- ~1600 veterinary products in Greener
- 199 official veterinary product monographs

### Enrofloxacin

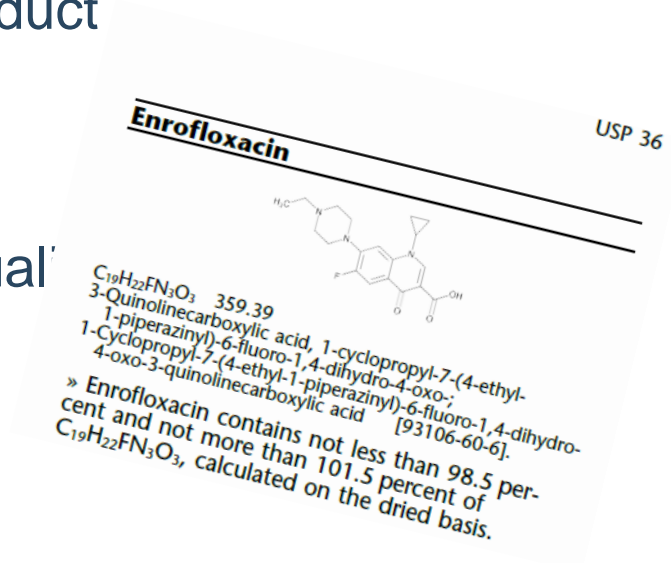
USP 36



$C_{19}H_{22}FN_3O_3$  359.39  
3-Quinolonecarboxylic acid, 1-cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-; 1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid [93106-60-6].  
» Enrofloxacin contains not less than 98.5 percent and not more than 101.5 percent of  $C_{19}H_{22}FN_3O_3$ , calculated on the dried basis.

## Substance Monographs

- USP grade API when no approved product available
  - Cisapride, potassium bromide, guaifenesin
- Known identity, purity, strength, and quality
- Known potency range
  - Compare to Certificate of Analysis
- Known acceptance criteria for quality assurance



## Compounding Expert Committee

- Identify need
- Develop preparation monograph

## Nomenclature Safety Labeling Expert Committee

- Approve preparation name
- [Drug] Compounded [Route of administration]  
[Dosage form], Veterinary

## Veterinary Compounded Preparation Monographs

- 5 currently official
- 7 to be balloted by Expert Committee
- 3 to be proposed in PF 40(2) Mar/Apr 2014

## Source:

- American Veterinary Medical Association
- Society of Veterinary Hospital Pharmacists
- International Academy of Compounding Pharmacists

## Prioritizing for 2015-2020 Cycle

## General Chapters

- Standards to ensure:
  - Consistent preparation and quality control
  - Minimized risk
  - Personnel training
  - Detailed documentation
  - Engineering controls
  - QA and Testing

Incentives for AHI to donate product monographs

Identify API substances for which:

- There is no approved product
- Use of an API in compounding is medically necessary

Continue to define universe of most commonly prepared veterinary compounds

Incentives for sponsors of compounded preparation monograph stability studies

Watch for veterinary compounding legislation (503-V)



THANK  
YOU!